

Ex. 8

Talc

What is talc?

Talc, hydrous magnesium silicate, is a soft mineral used in food, drugs, cosmetics and industrial applications. Cosmetic-grade talc is produced so that it conforms to United States Pharmacopeia (USP) and industry specifications.

Why is talc used in cosmetics and personal care products?

Talc has many uses in cosmetics and personal care products including as an absorbent, anti-caking agent and to improve the feel of the product. It is also used as a color additive and an inactive ingredient. Talc is approved by the Food and Drug Administration for use in ingested and topical drug products.

Is talc safe for use in cosmetics and personal care products?

Health experts have maintained over the years that products containing talc are safe when used as directed, and recent scientific reviews of available data have supported this position. The Food and Drug Administration has determined that talc is Generally Recognized As Safe (GRAS) for use as an anti-caking agent in foods. It is also permitted as an anti-caking agent in vanilla powder.

FDA has listed talc as a color additive that may be used in coloring drug products and as a component of colors for use in drugs and cosmetics.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRS...>

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Does talc contain asbestos fibers?

Cosmetic-grade talc does not contain asbestos, which is confirmed by X-ray diffraction, and optical and electron microscopy. In addition, the producers of cosmetic-grade talc have established purity specifications to ensure that it does not contain residue levels of asbestos.

Does talc cause respiratory effects when inhaled?

To help prevent inhalation by consumers, talc used in loose powder products in the United States is milled to a relatively large, non-respirable particle size ($>5\ \mu\text{m}$).

The inhalation safety of talc has been studied by the National Toxicology Program (NTP). While a study on test animals inhaling large doses of talc over two years showed some animals developing adverse health effects, the experts attending the ISRTP/FDA Talc workshop concluded that this study is not relevant to predicting human risk because it exceeded the maximum functionally tolerated dose, which means that it exceeded the ability of the test system to produce meaningful results. The exposure levels were so high that they resulted in particle overload in the lungs. Therefore, the lung tumors that were observed in some test animals were most likely related to chronic toxicity as a result of particle overload, rather than a direct effect of talc. This means that it is entirely possible that the observed effect would have been seen with other particulate substances tested in a similar manner, regardless of the nature of the material tested.

What about a possible link between talc use and ovarian cancer?

The National Toxicology Program (NTP) deferred consideration of listing Talc in its Report on Carcinogens after a review in 2000 found considerable confusion over the mineral nature and consequences of exposure to Talc, both containing asbestiform fibers and not containing asbestiform fibers. In October 2005, the NTP withdrew Talc from review, explaining that it had

become evident that the literature on both forms of Talc, with a few exceptions, provided an inadequate characterization of the actual materials under study to enable one to reach definitive conclusions concerning the specific substances responsible for the range of adverse health outcomes reported. A meta-analysis published in 2007 by Muscat and Huncharek shows no association between perineal (genital area) use of talc and ovarian cancer. However, a number of case-control epidemiology studies in the 1990's reported small increases in ovarian cancer among women who use talc in the perineal area. Among nine studies reviewed by the 1994 International Society of Regulatory Toxicology and Pharmacology (ISRTP)/FDA workshop regarding consumer uses and health perspectives of Talc, eight studies found relative risks of 1.6 or less, and one had a non-significant relative risk of 3.9. The relative risks less than 2 are generally considered insufficient to establish biological significance.

The one study with a non-significant relative risk of 3.9 cannot be separated from random error because it was based on only seven cases and three controls that used dusting powder. Additional epidemiology studies, completed since the ISRTP/FDA workshop, do not provide support that perineal talc use is associated with ovarian cancer.

The experts attending the ISRTP/FDA Talc workshop concluded that the epidemiology studies did not demonstrate a real association between talc and ovarian cancer. Studies completed since the 1994 workshop do not provide evidence that talc is carcinogenic, or is a causative factor in the development of ovarian cancer in humans.

What about the IARC re-assessment of Talc?

The International Agency for Research on Cancer (IARC) scheduled re-evaluation of talc during 2006. Previous evaluations classified talc not containing asbestiform fibers as "not classifiable as to its carcinogenicity to humans" (Group 3) in 1987. Talc (not containing asbestos) had been given a low priority for re-evaluation.

While the report from the IARC meeting has not been published, preliminary reports are that for Inhalation (Industrial) Talc, the human data were concluded to be "inadequate"; the animal data were concluded to be "limited" (one study only); therefore it was classified as - "not classifiable as to its carcinogenicity to humans;" For perineal use of talc-based Body Powder, the human data was concluded to be "limited"; and there was no animal data, therefore the evidence was "inadequate."

IARC posted "Summarized Evaluations" at <http://monographs.iarc.fr/ENG/Meetings/93-talc.pdf>. The rational sections for the summaries have not been published.